



UnitedHealthcare Pharmacy
Clinical Pharmacy Programs

Program Number	2020 P 3101-5
Program	Step Therapy
Medication	Elidel® (pimecrolimus) and Protopic® (tacrolimus)
P&T Approval Date	9/2017, 9/2018, 8/2019, 9/2020, 12/2020
Effective Date	3/1/2021; Oxford only: 3/1/2021

1. Background:

Elidel (pimecrolimus) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of mild to moderate atopic dermatitis in non-immunocompromised adults and children 2 years of age and older, who have failed to respond adequately to other topical prescription treatments, or when those treatments are not advisable. Protopic (tacrolimus) is indicated as second-line therapy for the short-term and non-continuous chronic treatment of moderate to severe atopic dermatitis in non-immunocompromised adults and children, who have failed to respond adequately to other topical prescription treatments for atopic dermatitis or when those treatments are not advisable.

Both Elidel and Protopic have demonstrated efficacy in the treatment of plaque psoriasis, and the American Academy of Dermatology recommend Elidel and Protopic for specific cases of facial and intertriginous psoriasis or situations where a topical corticosteroid may be associated with skin atrophy³.

Step Therapy programs are utilized to encourage the use of lower cost alternatives for certain therapeutic classes. If a member has a prescription for a topical corticosteroid in claim's history in the previous 365 days, the prescription for Elidel or Protopic will process automatically. Elidel or Protopic as documented in claims history will be allowed continued coverage of their current therapy. Members new to therapy will be required to meet the below criteria.

2. Coverage Criteria^a:

A. Elidel or Protopic will be approved based on **ONE** of the following criteria:

1. History of failure, contraindication, or intolerance to **one** topical corticosteroid[^]

-OR-

2. Drug is being prescribed for the facial or groin area

Authorization will be issued for 12 months.

^a State mandates may apply. Any federal regulatory requirements and the member specific benefit plan coverage may also impact coverage criteria. Other policies and utilization management programs may apply.

^Tried/failed alternative(s) are supported by FDA labeling

3. Additional Clinical Programs:

- Notwithstanding Coverage Criteria, UnitedHealthcare may approve initial and re-authorization based solely on previous claim/medication history, diagnosis codes (ICD-10) and/or claim logic. Use of automated approval and re-approval processes varies by program and/or therapeutic class.
- Supply limits may also be in place.

4. References:

1. Elidel [Package Insert]. Bridgewater, NJ: Valeant Pharmaceuticals Inc; December 2017.
2. Protopic [Package Insert]. Northbrook, IL: Astellas Pharma US, Inc; February 2019.
3. Menter A, Korman NJ, et al. “Guidelines of care for the management of psoriasis and psoriatic arthritis. Section 3. Guidelines of care for the management and treatment of psoriasis with topical therapies.” J Am Acad Dermatol 2009;60:643-59.

Program	Step Therapy – Elidel and Protopic
Change Control	
9/2017	New program.
9/2018	Annual Review. Updated references.
8/2019	Annual Review. Updated references, adding citation for the American Academy of Dermatology recommendation. Added statement regarding use of automated processes. Added statement that purpose of step therapy is to promote lower cost alternatives. Corrected spelling and formatting.
9/2020	Annual Review. Updated references.
12/2020	Added addendum regarding FDA labeled first line requirements